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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEDI-13	8069

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,408	GONZALES ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-36 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of the amendment filed on 09/21/2007. Upon entering the amendment, claims 27 and 47 are presently amended. In view of these amendments, the pending claims are 27-36 and 47-50 and presented for examination.

Response to Arguments

2. Applicant's arguments filed on 09/21/2207 with respect to claims under 35 U.S.C. 102(b) have been fully considered but they are not persuasive. The 102(b) rejections are maintained and made **FINAL**.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27, 32-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel (US 4,687,662).

With respect to claims 27, 32-36 and 47-50, the '662 patent discloses a method for oral administration of effervescent composition in the form of tablets or powders comprising a therapeutic agent, a granulating agent, a microparticulate effervescent component and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent (see column 3, lines 10-12 and abstract). And also the granulating agent may be selected from group

consisting of water, alcohol, sucrose, hydroxypropyl cellulose and causes slow disintegration of therapeutic agent and release gas (see column 4, lines 17-28). The effervescent system may comprise one or more components, preferably a carbonate containing material and an acid and mixtures thereof. The acids which may be employed are compounds capable of reacting with carbonate containing materials to cause the release of carbon dioxide when contacted with sufficient water (see column 5, lines 14-18 and lines 45+). The oral administration of effervescent composition advanced by Schobel provides granulating agents such as water, alcohol, sucrose, hydroxypropyl cellulose and natural and artificial sweeteners. Since the essential elements of the cited reference are identical to the instant claims (i.e. gas dispersing component including a solid matrix), would inherently have the same physiochemical properties as set forth in the instant application. As such the method for oral administration advanced by Schobel anticipates the instant claims set.

Applicant's arguments filed on 09/21/2007 have been fully considered but they are not persuasive.

Applicant asserts that Schobel does not disclose both a gas-dispersing component including a solid matrix having a first gas contained therein and an effervescent component that generates a second gas.

This is not found persuasive because in Schobel the therapeutic effervescent system comprising additional additives such as lubricants, sweeteners and glidants and thereof would constitute towards the formation of solid matrix and further the resultant blend is then formed into effervescent tablets. The additional sweetener includes sugars

such as sucrose, glucose, invert sugar, fructose, and mixtures thereof. Saccharin and its various salts such as sodium or calcium salt; cyclamic acid and its various salts and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol and the like. The sweeteners are used in amounts of up to about 5% by weight (see col. 6, lines 25-45). Even though these additional additives are not listed as a solid matrix having a first gas, as recited in the instant claim, the same compounds (i.e. compounds that are employed to form solid matrix, the dispersing component which releases at least one first gas) would inherently have the same physiochemical properties as set forth in the instant application and accordingly serve as dispersing component to release at least one first gas.

Gleaning from applicant's specification at page 5, lines 1-11 a first gas is generated by contact of gas-dispersing component to release or erupt gas. Thus, this component generally comprises water-soluble ingredients, such as carbohydrates, saccharides of simple sugars and sugar derivates, non-sugar sweetener, non-sweeteners, and the like. Similarly the prior art, Schoble discloses carbohydrates such as sugars, sucrose, glucose, invert sugar, fructose, and mixtures thereof; saccharin and its various salts and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like (col. 6, lines 25-40). These components in contact with water would also generate a gas, so that Schobel discloses the first gas.

And further, the effervescent system comprises a carbonate containing material and an acid. When introduced to water, the carbonate containing compound reacts with the acidifying agent to produce a rapid evolution of carbon dioxide gas. This rapid

evolution of gas stirs the solution dispersing the therapeutic agent. The stirring is intended to solubilize the therapeutic agent. This meets the limitation of an effervescent component that generates a second gas. The essence of dispersing a first gas and the gas generating component that reacts to produce second gas, and both gases of which are released into the liquid vehicle, will enhance distribution and dispersion of the medicament to form a clear solution. Therefore, Schobel does, not only disclose a first gas but also discloses the gas-generating effervescent component to generate a second gas.

Examiner agrees regarding Schobel disclosure at column 5, lines 14-18 and 45-64, but however, Schobel does disclose a gas-dispersing component, a gas-generating effervescent component and a medicament which is the same as recited in the instant claim.

3. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Wehling et al. (US 5,223,264).

Wehling discloses an oral effervescent dosage forms for the administrating a mixture of at least one effervescent disintegrating agent, and a pediatrically effective amount of at least one intended ingredient in the form of tablet (see column 2, lines 31-45). The effervescent agent includes compounds, which evolve gas by means of chemical reactions, which takes place upon exposure of the effervescent agent to produce carbon dioxide, oxygen or other gases (which are pediatrically safe) upon contact with water including saliva or simple gastric fluids. The said effervescent agent is effective both to aid in the rapid disintegration of tablet and provide a positive

organoleptic sensation to children (column 5, lines 9-38). The dosage form further includes one or more additional adjuvants such as cellulose materials (methyl cellulose and sodium carboxy methyl cellulose), polysaccharides, sugars, invert sugars and the like (see column 6, lines 50-54). The tablets include surface markings, cuttings, grooves, and letters and or numerals for the purpose of easy consumption by child (see column 3, lines 54-60). And also discloses a process of administering intended ingredient medicament to a child, so that tablet disintegrate in the child's mouth to provide a controlled drug delivery system and increased absorption of drug (see column 3, lines 29-29).

The oral administration of effervescent composition advanced by Wehling provides additional adjuvants such as cellulose materials (methyl cellulose and sodium carboxy methyl cellulose), polysaccharides, sugars, invert sugars and the like. Since the essential elements of the cited reference are identical to the instant claims (i.e. gas dispersing component including a solid matrix), would inherently have the same physiochemical properties as set forth in the instant application. As such the method for oral administration advanced by Wehling anticipates the instant claims set.

Applicant's arguments filed on 09/21/2007 have been fully considered but they are not persuasive.

Applicant asserts that Wheling does not disclose a gas-dispersing component including a solid matrix having first gas and a gas-generating effervescent component including components reactive with an aqueous vehicle to generate a second gas.

This is not found persuasive because in Wheling the therapeutic effervescent system comprising additional additives such as lubricants, sweeteners and glidants and thereof would constitute towards the formation of solid matrix and further the resultant blend is then formed into effervescent tablet of a size and shape adapted for direct oral administration to children. And the additional adjuvants e.g. binders include cellulose materials such as methyl cellulose and sodium carboxy methyl cellulose, alginic acids and salts thereof, polysaccharide acids, sugars invert sugars and the like (see col. 6, lines 48-55). Even though these additional additives are not listed as a solid matrix having a first gas, as recited in the instant claim, the same compounds (i.e. compounds that are employed to form solid matrix, the dispersing component which releases at least one first gas) would inherently have the same physiochemical properties as set forth in the instant application and accordingly serve as dispersing component to release at least one first gas.

And further, the effervescent system comprises a an acid sources or acid may be any which are safe for human consumption and may generally include food acids, acid anhydrides and acid salts. Carbonate sources include dry solid carbonate and bicarbonate salts. The amount of effervescent agent useful for the formation of tablets ranges from about 5 to 50% by weight (see col. 5, lines 15-65). Therefore, Wheling does, not only disclose a first gas but also discloses the gas-generating effervescent component to generate a second gas.

Where the general conditions/components of a claim are disclosed in the prior art, it is not inventive to discover the optimum or combining components by routine experimentation.

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the, shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
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